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Form Approved
OMB No. 0920-0891
Exp. Date 12/31/2021

Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center (WTC) Health Program

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

General Instructions

Any interested party may petition the WTC Program Administrator to add a condition to the List of WTC-Related Health Conditions (List) in 42 C.F.R. Part 88 (see http://www.cdc.gov/wtc/faq.html#hlthcond for the complete list).

Please use this form to petition the Administrator to add a health condition (any recognized medical condition requiring treatment or medication) to the List. Please use a separate form for each health condition.

Use of this petition *form* is voluntary, but any petition must include all of the information identified below, as required by 42 C.F.R. Part 88. Petitions that do not provide the required information will not be considered by the WTC Program Administrator. Additional supporting materials may be submitted and are encouraged.

Please note, however, the petition and all supporting materials submitted to the WTC Health Program are part of the public record and may be subject to public disclosure. Personal information will be redacted prior to public disclosure.

Please TYPE or PRINT all information clearly on the form.

If you need more space to provide the required information, please attach additional pages to this form.

Mail or email this form to: World Trade Center Health Program
395 E. Street, S.W., Suite 9200
Washington, D.C. 20201
WTC@cdc.gov

A. Interested Party Information

A1. Do you represent an organization (are you submitting this petition on behalf of an organization)?
☐ Yes (Go to A2) ■ No (Go to A3)

A2. Organization Information:

Name of organization

A3. Name of Individual Petitioner or Organization Representative:

[redacted]
First name Last name

Position, if representative of organization

A4. Mailing Address:

[redacted]
Street
[redacted]
City State Zip code

A5. Telephone Number: [redacted]

A6. Email Address: [redacted]

B. Proposed WTC-Related Health Condition Information

B1. Health Condition Information:

ANTI GBM DISEASE GLOMERULONEPHRITIS (ANTI-GLOMERULAR BASEMENT MEMBRANE DISEASE)

Name of health condition you wish to petition to add to the List of covered conditions

PLEASE REFER TO EXHIBIT A ATTACHED FOR DETAILS

If the name of the condition is not known, please provide a description of the condition or the name of the diagnosis provided by a physician or other healthcare provider.

C. Basis for Proposing that the Condition Be Added to the List of WTC-Related Health Conditions

C1. Describe the reasons the WTC Program Administrator should consider the addition of this health condition. Explain how the health condition you are proposing relates to the exposures that may have occurred from the September 11, 2001, terrorist attacks. Your explanation must include a medical basis for the relationship/association between the 9/11 exposure and the proposed health condition. The medical basis may be demonstrated by reference to a peer-reviewed, published, epidemiologic study about the health condition among 9/11 exposed populations or to clinical case reports of health conditions in WTC responders or survivors. First-hand accounts or anecdotal evidence may not be sufficient to establish medical basis. If you need more space, please attach additional pages to this form.

PLEASE REFER TO EXHIBIT A ATTACHED FOR DETAILS

D. Signature of Petitioner

Sign your name below to indicate that you are petitioning the WTC Program Administrator to consider adding a health condition to the list of WTC-related health conditions identified in 42 C.F.R. Part 88.

[redacted]

2/24/2020

Signature Date

Privacy Act Statement

In accordance with the Privacy Act of 1974, as amended (5 U.S.C. § 552a), you are hereby notified of the following:

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 amended the Public Health Service Act (PHS Act) to establish the World Trade Center (WTC) Health Program. Sections 3311, 3312, and 3321 of Title XXXIII of the PHS Act require that the WTC Program Administrator develop regulations to implement portions of the WTC Health Program established within the Department of Health and Human Services (HHS). The WTC Health Program is administered by the Director of the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention (CDC). The information provided with this form and supporting documentation will be used by the WTC Program Administrator to consider the disposition of a petitioned-for health condition. Disclosure of this information is voluntary.

Records containing information in identifiable form become part of an existing NIOSH system of records under the Privacy Act, 09-20-0147, "Occupational Health Epidemiological Studies and EEOICPA Program Records and WTC Health Program Records, HHS/CDC/NIOSH." These records are treated in a confidential manner, unless otherwise compelled by law.

Information submitted to WTC Health Program which may be considered "protected health information" pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191; 42 U.S.C. § 1320d) and the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules (45 C.F.R. pts. 160, 162, and 164) will be maintained in accordance with all applicable laws.

NIOSH may disclose information in identifiable form only insofar as such disclosure is permitted pursuant to the HIPAA Privacy Rule; this may include disclosure to the WTC Health Program Scientific/Technical Advisory Committee (STAC), which may be asked to consider the petition and issue a recommendation to the WTC Program Administrator. Information in identifiable form will be redacted from submitted petition forms and supporting documentation that become a part of the public record (e.g. in conjunction with STAC consideration or a rulemaking).

EXHIBIT A [redacted]

PETITION TO ADD A HEALTH CONDITION TO THE LIST OF WTC-RELATED HEALTH CONDITIONS

DATE: February 24, 2020

World Trade Center Health Program
395 East Street, S.W., Suite 9200
Washington, D.C. 20201

ATTN: World Trade Center (WTC) Health Program Policy Coordinator or designee

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1 INTERESTED PARTY NAME AND CONTACT INFORMATION

1A [redacted]

WTC World Health Fund Registration ID# [redacted]

2 NAME AND DESCRIPTION OF CONDITION TO BE ADDED

2A ANTI GBM DISEASE (ANTI-GLOMERULAR BASEMENT MEMBRANE DISEASE) GLOMERULONEPHRITIS

Definition of Anti-GBM: Anti-GBM disease is a disease that occurs as a result of injury to small blood vessels (capillaries) in the kidneys and/or lungs. *Autoantibodies* are antibodies directed toward the body itself (rather than towards something foreign such as bacteria or viruses). In Anti-GBM disease, these autoantibodies are targeted to the *basement membrane*, which is part of the wall of these capillary blood vessels in the kidneys and lungs. The name Anti-GBM disease reflects the fact that this disease is caused by autoantibodies targeting and causing damage to (anti-) the glomerular basement membrane (GBM). The term Goodpastures is used when Anti-GBM disease reaches the lungs.

SOURCE: "Anti-GBM Disease." UNC School of Medicine. www.unckidneycenter.org/
https://unckidneycenter.org/kidneyhealthlibrary/glomerular-disease/Anti-GBM-disease/

My diagnosis: In January of [redacted] with symptoms of extreme lethargy, I went to see my primary doctor. A blood test indicated a high creatine level. I was hospitalized and a kidney biopsy confirmed: Anti-GBM Glomerulonephritis, MILD (20%) Interstitial Fibrosis, Tubular Atrophy and Global Glomerular Sclerosis, and Severe Arterial Sclerosis. Serologic workup showed elevated Anti-GBM (112). 7 out of 20+ Glomeruli had cellular crescents.

Treatment: 1) *Therapeutic plasmapheresis/leukapheresis* was the initial treatment, to remove the circulating pathogenic Anti-GBM antibodies. 2) *Prednisone* to attenuate the pathogenic antibody-mediated glomerular inflammatory responses. 3) *Chemotherapy* drug cyclophosphamide was administered via infusion to further suppress the production of pathogenic Anti-GBM antibodies. 4) *Furosemide* for anasarca edema. 5) ESA clinic for Procrit injection for anemia resulting from Anti-GBM.

Lifelong effects: Chronic kidney disease stage 3, platelet dysfunction (bleeding disorder), fatigue, muscle cramps, crescentic glomerulonephritis, possible relapse.

3 REASON FOR ADDING THE CONDITION WITH MEDICAL BASIS FOR THE ASSOCIATION BETWEEN THE SEPTEMBER 11, 2001, TERRORIST ATTACKS AND THE CONDITION.

3A *REASON* ANTI-GBM SHOULD BE ADDED TO THE WTC LIST OF HEALTH-RELATED CONDITIONS.

There is a direct connection of hydrocarbon exposure and the onset of Anti-GBM disease.

Anti-GBM disease is very rare. It affects 1 in a million individuals. There is very little known about the cause apart from the association of hydrocarbon exposure and an onset of the disease.

The only time I was exposed to toxic air with hydrocarbons was during the 9/11 terrorist attack. The heaviest exposure was between 9/11 and December of 2001.

Research studies I've found in multiple scientific journals agree that there is a direct association between hydrocarbon exposure and the onset of Anti-GBM.

- In this petition I present information on my exposure as a resident and business owner in the WTC area.
- I offer supporting evidence from epidemiological studies on the toxic air quality in the WTC community during 9/11.
- I offer supporting evidence from several scientific studies on the association between hydrocarbon exposure and the onset of Anti-GBM disease, *including evidence based on Hill's criteria for causality*.

3B *MEDICAL BASIS* FOR THE ASSOCIATION BETWEEN THE SEPTEMBER 11, 2001, TERRORIST ATTACKS AND THE CONDITION.

3B-1: My Exposure

I lived in Battery Park City at [redacted] (where my condominium apartment faced the WTC) and worked one block from the WTC at [redacted] (corner of Broadway). When I was able to return to my apartment and my business [redacted] experienced choking smoke odors, the feel of a gritty taste in my mouth from the dust that permeated the air for months, ID checkpoints, National Guardsmen everywhere. Both my apartment and office displayed WTC dust.

Walking from my home to office each day, although I attempted to cover my mouth, I was unable to escape the overpowering odor that lingered in the air and continued to taste the gritty dust in my mouth as ground zero continued to smolder for months.

Due to my participation in [redacted] (a grass roots organization formed to assist small business owners in recovery from 9/11), I was asked to participate in a Hunter College Environmental Air Quality study. I wore a gadget around my neck for a few weeks to collect air samples. The result of the report indicated *I was exposed to extremely high levels of several toxins, and specifically large amounts of Benzene, a VOC* (volatile organic compound).

Over the years I continued to be extremely depressed because of the site of Ground Zero along my walk to and from work and from my apartment view, which made me relive the event daily. I eventually had to escape the mental distress, by moving from Manhattan, where I had lived for [redacted]

> "When the towers came down...they released a massive plume of carcinogens, turning lower Manhattan into a cesspool of cancer and deadly disease. "We will never know the composition of that cloud, because the wind carried it away, but people were breathing and eating it," [said the World Trade Center Health Program's Dr. Michael Crane]. "What we do know is that it had all kinds of god-awful things in it. Burning jet fuel. Plastics, metal, fiberglass, asbestos. It was thick, terrible stuff. A witch's brew."
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> Because the fires burned at Ground Zero for more than 90 days, a later study explained that the contaminants found in the dust immediately after the attacks continued to show up in samples for weeks."

SOURCE: Bankoff, Caroline. "What We Know About How 9/11 Has Affected New Yorkers' Health, 15 Years Later." New York Magazine, September 10, 2016, www.nymag.com/ https://nymag.com/intelligencer/2016/09/15-years-later-how-has-9-11-affected-new-yorkers-health.html

3B-2: Supporting Evidence on the Toxic Air Quality

"Measuring and maximizing coverage in the World Trade Center Health Registry."

"Residents, including adults and children, of lower Manhattan on 11 September 2001 whose primary residence was close to the disaster site may have had an increased risk of exposure to potentially toxic contaminants if they were at home at any time between 11 September and 31 December 2001. Many residents were also displaced from their homes, had concerns about toxic exposures, and had potential exposure to physical injury or psychological impact and/or rescue and clean-up efforts."

SOURCE: Murphy, Joe etal. "Measuring and maximizing coverage in the World Trade Center Health Registry." Wiley InterScience, 2007, www.interscience.wiley.com

"Mount Sinai Pediatric Environmental Health Specialty Unit WTC Volatile Organic Compounds Fact Sheet"

Were *volatile organic compounds* released into the environment after the collapse of the World Trade Center?

VOCs were released into the air from the fires at the World Trade Center due to the evaporation of fumes from burning paint, plastics, furniture, papers, carpeting and jet fuel.

Levels of VOCs were elevated while the fires were still burning at the World Trade Center site, *in the period from September 11th through the end of December 2001.*

... In their measurements, the EPA was able to detect a total of 51 VOCs, primarily within the World Trade Center clean-up site. *Benzene, a chemical widely used in the United States, was one volatile organic compound monitored by the EPA.*

SOURCE: "Mount Sinai Pediatric Environmental Health Specialty Unit." WTC Volatile Organic Compounds.pdf WTC Volatile Organic Compounds Fact Sheet. https://icahn.mssm.edu/files/ISMMS/Assets/Research/PEHSU/WTC 20Volatile 20Organic 20Compounds.pdf

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"Pollution and Deception at Ground Zero"

Chemicals that cause cancer, *weaken the immune system* or affect the reproductive system are "stealth" invaders of the body. *Many of the effects of human exposure to the WTC pollution will not manifest for many years.*

SOURCE: Suzanne Mattei, "New York City Executive for the Cierra Club," https://www.gothamgazette.com/rebuilding_nyc/sierraclub_report.pdf

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3B-3: Supporting Evidence on the Association Between Exposure and the Onset of Anti-GBM Disease

"Hydrocarbon exposure may cause glomerulonephritis and worsen renal function: evidence based on *Hill's criteria for causality*"

An association between hydrocarbon exposure and glomerulonephritis, the commonest cause of end-stage renal disease, was reported already in 1894 up to 1975, the association was mentioned in sporadic case reports, but after the publication of the first case-control study by Zimmerman et al., research has accelerated. Many case-control studies have now shown that a large proportion of patients with glomerulonephritis have had frequent and heavy exposure to hydrocarbons... the nephritogenic effect of hydrocarbons has been proved in several cross-sectional and experimental studies.

Hydrocarbon exposure may either initiate glomerulonephritis *(hypothesis I)* or worsen renal function *(hypothesis II),* or both. ... *these two hypotheses are tested separately using Hill's criteria for causality.*

In previous studies and reviews, most discussions have concerned possible bias that may have distorted the results, and rightly so. But attention should also be paid to the striking consistency of the findings. With one exception, all of Hill's criteria for causality (Table 1) have been fulfilled for both hypotheses, and as stressed by Hill, lack of specificity should not be overemphasized if other, more important criteria are in accordance. Also, the unsupportive case-control studies, that have raised doubt about the role of hydrocarbon exposure, were in fact supportive because

they included only acute or early cases, or they had unexposed patients with normal or near normal renal function and exposed patients with renal failure.

SOURCE: Ravnskov, U. "Hydrocarbon exposure may cause glomerulonephritis and worsen renal function: evidence based on Hill's criteria for causality." QJM: An International Journal of Medicine, Volume 93, Issue 8, Pages 551–556, August 2000. https://doi.org/10.1093/qjmed/93.8.551

"Anti-glomerular basement membrane disease."

"... Exposure to hydrocarbons has been associated with the onset of symptoms, and case control studies have shown higher levels of Anti-GBM antibodies (at borderline levels) in individuals exposed to inhaled hydrocarbons ..."

SOURCE: Pusey, Charles D. "Anti-glomerular basement membrane disease." Official Journal of the International Society of Nephrology, October 2003, www.kidney-international.org/https://www.kidney-international.

"A Mini-Epidemic of anti-glomerular basement membrane disease: Clinical and epidemiological study."

"Environmental factors have long been implicated to play a role in triggering the disease." ... "A few case reports have found causal relationship linking Anti-GBM disease to hydrocarbon exposure, thus implicating occupational exposure as a trigger."

SOURCE: Lingarag, Umesh etal. "A Mini-Epidemic of anti-glomerular basement membrane disease: Clinical and epidemiological study." Saudi Journal of Kidney Diseases and Transplantation. 2017, www.sjkdt.org/ http://www.sjkdt.org/article.asp?issn=1319-2442;year=2017;volume=28;issue=5;spage=1057;epage=1063;aulast=Lingaraj

"Anti-Glomerular Basement Membrane Disease"

"Environmental factors are thought to play a role in triggering the disease. possibly volatile hydrocarbon solvents.

Most patients without treatment died shortly after diagnosis of Anti-GBM disease; the survival rate at 12 months was 4%, and the renal survival rate was 2% (Benoit et al., 1963). Although mortality has improved by the introduction of intense immunosuppression, renal survival remains very poor because of the delayed diagnosis of Anti-GBM disease or delayed initiation of induction therapies. Fortunately, my case was detected in its early stage, preventing Goodpastures".

SOURCE: Kouichi Hirayama and Kunihiro Yamagata Tokyo Medical University Ibaraki Medical Center, University of Tsukuba Japan. /https://www.intechopen.com/